Medical Devices

October 2009

FDA and the DG Enterprise are engaged in both bilateral and multilateral discussions to harmonize regulation of medical devices. Based on a 2007 Memorandum of Confidentiality which permits the exchange of confidential information on regulated products between U.S and EU regulators, in September 2009, officials from the FDA and the European Commission discussed a process for recognition of inspection audits. This process will continue through talks with EU member states and the Notified Bodies. The FDA agreed to provide the Commission with draft guidance and documents on implantable medical devices, reprocessing medical devices, and cellular products. Both sides agreed to develop a joint workshop on genetic testing (in-vitro diagnostic testing devices) and to work on establishing a system for unique device identification and traceability requirements.

November 2007

Earlier this year, the U.S. Food and Drug Administration (FDA) and the European Commission concluded confidentiality arrangements and a joint work plan in the areas of cosmetics and medical devices. In addition, the previously signed cooperation arrangement and joint work plan between the FDA, the European Commission, and the European Medicines Agency in the areas of human and animal drugs and human biologics was renewed and expanded. These arrangements will expand bilateral cooperation, ease regulatory burdens while maintaining high standards of public health protection, and facilitate the promotion of public health by the introduction of new products through intensified upstream regulatory cooperation in these product categories.